



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: Y.-M. Lo, et al.

Serial No.: 09/872,063

Group Art Unit: 1634

Filing Date: June 1, 2001

Examiner: Jeanine Anne Goldberg

For: **NON-INVASIVE PRENATAL  
DIAGNOSIS**

**EXPRESS MAIL INFORMATION**

EXPRESS MAIL LABEL NO: EL 964553562 US

DATE OF DEPOSIT: 16 December 2003

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 C.F.R. §§ 1.56 and in accordance with 37 C.F.R. §§ 1.97 and 1.98, information relating to the above-identified application is hereby disclosed, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed on the PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 submitted herewith.

Inclusion of the information submitted herewith is not to be construed as an admission that the information is material as that term is defined in 37 C.F.R. § 1.56(b).

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

**This Information Disclosure Statement is being filed:**

- ☐ within three months of the filing date of the patent application.
  - ☐ within three months of the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 of the international application.
  - ☐ before the mailing date of a first Office Action on the merits.
  - ☒ after the mailing date of a first Office Action on the merits, but before the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, and accordingly is accompanied by:
    - ☐ the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below);
- or**
- ☒ the Fee of \$180.00 set forth in 37 C.F.R. § 1.17(p); or
  - ☐ No fee is owed by the applicant(s).
- ☐ In accordance with 37 C.F.R. § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below) and the fee of \$180.00 as set forth in 37 C.F.R. § 1.17(p), is attached.
- ☐ after the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, but before, or simultaneously with, the payment of the Issue Fee, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e), a Petition requesting consideration of the Information Disclosure Statement and the Petition Fee of \$130.00 set forth in 37 C.F.R. § 1.17(i)(1) (see "Statement," "Petition," and "Fees" below).
- ☒ Copies of references AA-AO listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 are enclosed herewith

**EXCEPT THAT:**

- ☐ In view of the voluminous nature of references @@@, and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- ☐ In accordance with 37 C.F.R. § 1.98(d), copies of the following references listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application.

- ☐ Copies of references listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 were previously cited by or submitted to the U.S. Patent and Trademark Office in parent application Serial No. \_\_\_\_\_ filed on \_\_\_\_\_.
- ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

**Statement under 37 C.F.R. § 1.97(e)**

- ☐ The undersigned attorney hereby states that each item information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.

**Petition**

- ☐ Applicant(s) hereby petitions the Assistant Commissioner to consider the references listed in this Information Disclosure Statement, on the enclosed PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449, and the examination of the above-identified patent application.

**Fees**

- ☐ No Fee is owed by the applicant(s).
- ☒ The Information Disclosure Statement Fee of \$180.00 under 37 C.F.R. § 1.17(p) is enclosed herewith.
- ☐ The Petition Fee of \$130.00 under 37 C.F.R. § 1.17(i)(1) is enclosed herewith.

**Method of Payment of Fees**

- ☐ Attached is a check in the amount of \$\_\_\_\_\_. This form is submitted in duplicate.
- ☒ Charge Deposit Account No. 50-1275 in the amount of \$\_\_\_\_\_. This form is submitted in duplicate.
- ☒ Please charge any deficiency or credit any overpayment to Deposit Account 50-1275.

☐ No fee or Statement is required under 37 C.F.R. § 1.97(b).

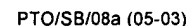
Respectfully submitted,



**Paul K. Legaard**  
**Registration No. 38,534**

Dated: December 16, 2003

COZEN O'CONNOR, P.C.  
1900 Market Street, 5<sup>th</sup> Floor  
Philadelphia, PA 19103-3508  
(215) 665-2000 -- Telephone  
(215) 701-2013 - Facsimile



Approved for use through 04/30/2003. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A P.T.O.

**Complete if Known**

(use as many sheets as necessary)

Sheet	1	of	3
-------	---	----	---

Application Number	09/872,063
Filing Date	June 1, 2001
First Named Inventor	Y.-M. Lo
Art Unit	1634
Examiner Name	Jeanine Anne Goldberg
Attorney Docket Number	BTG0010-100 (142480US02)

## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

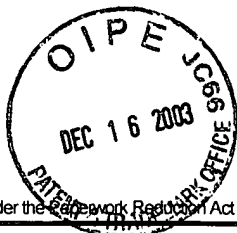
[illegible]

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

*If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.*



PTO/SB/08b(05-03)  
Approved for use through 04/30/2003. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE  
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

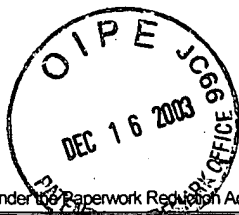
<b>Substitute for form 1449A/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		<b>Compleat if Known</b>			
		Application Number	09/872,063		
		Filing Date	June 1, 2001		
		First Named Inventor	Y.-M. LO		
		Group Art Unit	1634		
		Examiner Name	Jeanine Anne Goldberg		
Sheet	2	of	3	Attorney Docket Number	BTG0010-100 (142480US02)

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	AB	Lo, Application of PCR for fetal cell detection," Early Human Dev. (1996) 47:S73-S77.	
	AC	Lo, et al., "Two-way cell traffic between mother and fetus: biologic and clinical implications," Blood (1996) 88:4390-4395.	
	AD	Lo, "Non-invasive prenatal diagnosis using fetal cells in maternal blood," J. Clin. Pathol. (1994) 47:1060-1065.	
	AE	Lo, et al., "An improved PCR-based system for prenatal sex determination from maternal peripheral blood," Ann. N.Y. Acad. Sci. (1994) 731:214-216.	
	AF	Lo, et al., "Strategies for the detection of autosomal fetal DNA sequence from maternal peripheral blood," Ann. N.Y. Acad. Sci. (1994) 731:204-213.	
	AG	Lo, "Detection of minority nucleic acid populations by PCR," J. Pathol. (1994) 174:1-6.	
	AH	Lo, et al., "Detection of fetal RhD sequence from peripheral blood of sensitized RhD-negative pregnant women," Br. J. Haematol. (1994) 87:658-660.	
	AI	Lo, et al., "Non-invasive prenatal diagnosis," Lancet (1994) 343:802-803.	
	AJ	Lo, et al., "Prenatal determination of fetal RhD status by analysis of peripheral blood of Rhesus negative mothers," Lancet (1993) 341:1147-1148.	
	AK	Lo, et al., "Prenatal sex determination from maternal peripheral blood using the polymerase chain reaction," Hum. Genet. (1993) 90:483-488.	
	AL	Lo, et al., "Non-invasive approach to prenatal diagnosis from maternal peripheral blood," Prenat. Diagn. (1992) 12:547-548.	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.  
1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.  
This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



PTO/SB/08b(05-03)

Approved for use through 04/30/2003. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 3 of 3

**Complete if Known**

Application Number	09/872,063
Filing Date	June 1, 2001
First Named Inventor	Y.-M. Lo
Group Art Unit	1634
Examiner Name	Jeanine Anne Goldberg
Attorney Docket Number	BTG0010-100 (142480US02)

**OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	AM	Lo, et al., "Detection of single-copy fetal DNA sequence from maternal blood," Lancet (1990) 335:1463-1464.	
	AN	Lo, et al., "Prenatal sex determination," Lancet (1990) 335:724.	
	AO	Lo, et al., "Prenatal sex determination by DNA amplification from maternal peripheral blood," Lancet (1989) 2:1363-1365.	

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.